

### Remarks

Applicant has attended to the spelling of "sequestrant" in claim 10. Please withdraw this objection.

Applicants have amended the disclosure as suggested by the Examiner in order to effect incorporation by reference of GenBank Accession X04500. Thus, there is no new matter in the instant application. Please withdraw these objections.

Solely in order to expedite prosecution of the instant case, Applicants have amended the claims to comply with what the Examiner believes to be enabled (see Office Action at p. 5).<sup>1</sup> Support for these amendments may be found throughout the disclosure, e.g., on page 12, which discusses Applicants' findings that individuals homozygous for the T allele at position (-511) and the C allele at position (-31) of the IL-1 $\beta$  gene promoter may be predisposed to larger increases in total blood cholesterol levels upon treatment with rapamycin regimens. Please withdraw the outstanding enablement-based rejection of the pending claims.

Claim 16 has been amended to refer to identifying the nucleotide pair at the polymorphic site -31 T $\rightarrow$ C by determining the nucleotide pair at polymorphic site -511 C $\rightarrow$ T of the IL-1 $\beta$  gene, which is position 1423 of SEQ ID NO:11. Support for using -511 SNP to identify the polymorphism at -31 of the IL-1 $\beta$  gene may be found on pp. 20-21, where such data is specifically disclosed. Please withdraw the outstanding written description-based rejection of claim 16.

Applicants have amended the claims to remove the paranthesis from the pending claims. Please withdraw the outstanding indefiniteness-based rejection of the pending claims.

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<sup>1</sup> Applicants wish to comment on the Office's assertion on page 8 of the Office Action that the specification does not provide data for patients prior to immunosuppressant treatment. As noted in the specification at page 12, paragraph 2, during statistical analysis the absolute serum cholesterol level at last visit was defined as the dependent variable and the cholesterol level at baseline was the independent variable -- thus, automatically taking into consideration the baseline level.

## CONCLUSION

In light of the above amendments, observations and remarks, Applicants respectfully submit that the presently claimed invention satisfies 35 U.S.C. §112, and is neither disclosed nor suggested by any art of record. Accordingly, reconsideration and allowance of all claims in this application is earnestly solicited.

Applicants' undersigned attorney may be reached in our New Jersey office by telephone at (862) 778-9308. All correspondence should continue to be directed to our below-listed address.

Novartis Pharmaceuticals Corp.  
Patents Pharma  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-9308

Respectfully submitted,



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Leslie Fischer  
Attorney for Applicants  
Reg. No. 58,393

Date:

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